# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/GB05/001161

International filing date: 24 March 2005 (24.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: GB
Number: 0502287.6
Filing date: 04 February 2005 (04.02.2005)

Date of receipt at the International Bureau: 03 August 2005 (03.08.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse

PC7/GB2005/001161

INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed

Dated 25 July 2005

Patents Form 1/77

Patents Act 1977
(Rule 16)

# Request for grant of a patent

*(An explanatory leaflet on how to fill in this form is available from the Patent Office)*

The Patent Office
Cardiff Road
Newport
South Wales
NP10 8QQ

***Application number GB*** 0502287.6 - 4 FEB 2005

1. Your reference: *(optional)* P208181B

2. Full name, address and postcode of the applicant or of each applicant *(underline all surnames)*:

PEARSALLS LIMITED
TANCRED STREET
TAUNTON
SOMERSET
TA1 1RY

Patents ADP number *(if you know it)*: 7998941001

If the applicant is a corporate body, give the country/state of its incorporation: ENGLAND

3. Title of the invention: IMPROVEMENTS IN AND RELATING TO IMPLANTS

4. Name of your agent *(if you have one)*: URQUHART-DYKES & LORD

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*:

TOWER NORTH CENTRAL
MERRION WAY
LEEDS
LS2 8PA

Patents ADP number *(if you know it)*: 1644044 8857138001

5. Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s):

| Country | Application number *(if you know it)* | Date of filing *(day / month / year)* |
|---|---|---|

6. Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application? If so, please give the application number and filing date of the earlier application:

| Number of earlier UK application | Date of filing *(day / month / year)* |
|---|---|

7. Inventorship: (Inventors must be individuals not companies) (Please tick the appropriate boxes)

Are all the applicants named above also inventors? YES ☐ NO ☑

If yes, are there any other inventors? YES ☑ NO ☐

8. Are you paying the application fee with this form? YES ☑ NO ☐

## Patents Form 1/77



9. Accompanying documents: not counting duplicates, please enter the number of pages of each item accompanying this form:

| | |
|---|---|
| Continuation sheets of this form: | |
| Description: | 31 ✓ |
| Claim(s): | 3 ✓ |
| Abstract: | - |
| Drawing(s): | 7 ✓ |

If you are not filing a description, please give details of the previous application you are going to rely upon:

| Country | Application number | Date of filing (day / month / year) |
|---|---|---|

10. If you are also filing any of the following, state how many against each item.

| | |
|---|---|
| Priority documents: | |
| Statement of inventorship and right to grant of a patent (Patents Form 7/77): | |
| Request for search (Patents Form 9A/77): | |
| Request for substantive examination (Patents Form 10/77): | |
| Any other documents: (please specify) | |

11. I/We request the grant of a patent on the basis of this application.

Signature(s): Date: 04 FEB 2005

12. Name, e-mail address, telephone, Fax and/or mobile number, if any, of a contact point for the applicant: NEIL PAWLYN

**Warning**
After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you are resident in the United Kingdom and your application contains information which relates to military technology, or would be prejudicial to national security or the safety of the public, section 23 of the Patents Act 1977 prohibits you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

**Notes**
A leaflet on how to fill in this form is available from the Patent Office. If you would like a copy of the leaflet it is available on our website at http://www.patent.gov.uk/patent/info/fact05.pdf or alternatively you could telephone 08459 500505 or send an email to enquiries@patent.gov.uk to request a copy.

spiralling one or more further elements within the inner component and/or the inner

component may be formed by folded and/or bending and/or spiralling one or more parts within the outer component. The core may be within the inner component by virtue of the inner component extending for 360 degrees or more about a part of the core, for instance in one or more views and/or the inner component may be within the outer component by virtue of the outer component extending for 360 degrees or more about a part of the inner component, for instance in one or more views. In such embodiments the core may particularly be formed from an octagonal spiral, with a continuation of the octagonal spiral forming the inner component and a further continuation providing the outer component. The core and/or inner component and/or outer component in such an embodiment may be formed of different materials and/or formed in different ways and/or be provided with different properties. In particular the core may mimic the properties of the nucleus and/or the inner component may mimic the properties of the annulus, or properties intermediate the nucleus and annulus and/or the outer component may mimic properties of the annulus and/or the anterior longitudinal ligament(s). A core provided as a continuation of the inner component and/or outer component and/or an inner component provided as a continuation of the outer component may be provided with additional core material, such as an elastomeric material, visco-elastic material and/or hydrogel. Preferably core material in a form which can flow into and around the core and then set is so provided.

The core may be formed of a single material type or of multiple material types. The core may be an elastomeric material. The core may be a visco-elastic material. The core may be a hydrogel, particularly an elastomeric one. The core may include silicone based materials. The core may include materials having a Shore A hardness of 35 to 80°. The core may be impregnated and/or doped and/or provided with further materials. The further materials may be or include barium sulphate.

The core may be provided of fibrous material, for instance such material provided in a single plane. The fibrous material may be provided with a proportion, preferably the majority, of the fibres at an angle of between 10 and 80 degrees to the horizontal. Such a material may be provided of embroidery and/or other fibrous assembly technique. Preferably such a material resembles the structure and/or properties of the fibrous material of the spine. The core may be formed of a coiled material,

particularly a fibrous material. Such a fibrous material may be elastomeric and/or polyester and/or the other fibre materials mentioned herein.

Preferably the core provides equivalent properties and/or behaviour to the nucleus pulposus of a natural disc, for instance during compression and/or distraction and/or horizontal gliding and/or axial rotation and/or flexion and/or extension.

The core may provide a planar top surface and/or planar lower surface. The area of the top surface may be the same as the area of the lower surface. Preferably the top and bottom surfaces are not parallel to one another. Preferably the top and bottom surfaces are inclined relative to one another, ideally in a manner equivalent to a natural disc and/or its nucleus. Preferably the separation of the top and bottom surfaces increases from one side of the core to the other. Preferably the rate of increase in separation is even. Preferably the separation of the top and bottom surfaces increases from the anterior to the posterior side of the core. The top surface and/or bottom surface of the core may be octagonal and/or hexagonal and/or round and/or elliptic. The shape may be regular or irregular, for instance one or more sides of a octagon being larger than one or more others. Rounded corners to the shape are preferably provided.

The core is preferably provided with one or more sides extending between the top surface and the bottom surface. One, six or eight sides may particularly be provided. Where multiple sides are provided, preferably the pairs of opposing sides are provided. The sides may directly or indirectly oppose one another. Preferably opposing sides are parallel to one another, but potentially off set. Preferably the sides are planar. The sides may be vertically provided in use. The anterior side of the core may be of greater width than the posterior side of the core. The anterior side of the core may be of lesser height than the posterior side of the core. The edge of a side closer to the anterior side of the core may be shorter than the edge closer to the posterior side of the core.

The core may be narrower towards the anterior side than towards the middle thereof and/or the core may be narrower towards the posterior side than towards the middle

thereof. From anterior to posterior side, the core may have a portion of increasing width, a portion of constant width and a portion of decreasing width.

The core is preferably narrower in the anterior to posterior direction than it is wide, that is perpendicular to the anterior to posterior direction.

The interface between sides of the core and/or between the sides and bottom of the corer and/or between the sides and top of the core may be curved.

A particularly preferred form of the core is octagonal in cross-section, increases in thickness from the anterior side to the posterior side and has a shorter anterior side than posterior side. Preferably when viewed in plan, the core lies entirely within the plan of the disc it is to be used to replace.

The core and/or inner component may be provided according to the details of an implant according to the technique set out in applicant's UK Patent Application No 0406851.6 filed 26 March 2004 or the additional application filed there on under our reference P208007 on the same day as this application, the contents of which are incorporated herein by reference.

It is preferred that the anterior edge of the core is recessed relative to the anterior surface of the vertebral bodies and/or anterior edge of the disc prosthesis, preferably by at least 4mm. It is preferred that the centre of the core is provided and maintained at the centre of the disc space. The position of the core relative to the anterior surface of the vertebral bodies and/or anterior edge of the disc prosthesis and/or relative to the centre of the disc space may be maintained by the outer component and/or inner component and/or a spacing component. Preferably the outer component and/or inner component and/or spacing component also thus provide the flanges flush with the anterior surface of the vertebral bodies.

Preferably the position of the core is maintained by a spacing component. The spacing component may be a continuation of, and is ideally integral with, the inner component and/or outer component and/or additional elements. The spacing component is preferably a continuation of one or more of the side walls of the inner

component and inner component than between the inner component and core.

The inner component may entirely surround the core and/or encapsulate the core. One or more apertures or gaps are preferred in the inner component, ideally to provide fluid communication through the inner component. Preferably a large number of apertures or gaps are provided the material from which the inner component is formed, for instance a woven fabric. The apertures or gaps occurring in the inner component due to the manner of manufacture of the material from which it is formed may be supplemented with further apertures or gaps. The supplementation may be provided by degradation and/or absorption of one or more materials forming the inner component.

The inner component may be configured and/or formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth between the inner component and the core and/or through the inner component.

One or more materials used in the inner component may be bio-absorbable and/or soluble and/or degradable, particularly with the spine. The bio-absorbable material may be used to decrease the amount of inner component present and/or positions at which the inner component is present and/or density at which the inner component is present overtime. Areas of bio-absorbable material may be provided. Bio-absorbable fibres may be used to form the inner component. The inner component may be entirely bio-absorbable or only partially. Different materials having different rates of bio-absorption may be used. The may be mixed together in the inner component and/or may be used for particular areas thereof and/or in a particular sequence within the inner component. Slow, moderate and fast bio-absorption materials may be used. Preferably bio-absorption of the inner component is used to provide space for tissue ingrowth.

Preferably the inner component provides a smooth inner surface which potentially contacts the core. Preferably uniform contact between the inner surface of the inner component and the core is provided. Preferably the fibres forming the inner surface of the inner component are evenly positioned with respect to one another. Preferably any abrasion of the core by the inner component is distributed rather than localised. The inner component preferably provides a smooth inner fabric surface, and ideally

woven fibrous surface. A densely packed material may be used for the inner surface, ideally to provide the uniform contact surface with the core. The inner surface of the inner component may be of a different material and/or different configuration to the inside and/or outer surface of the inner component.

The inner component may be formed from a substantially planar element. The inner component may be so formed by folding and/or stitching and/or interdigitating one or more parts thereof. In particular, a top wall of the inner component may be connected to a side wall and hence to a bottom wall. One or more further side walls may be connected to the top wall and/or side wall and/or bottom wall. A series of side walls may be provided by an elongate part of the element. Folds or future folds may define one side wall relative to an adjacent side wall or walls.

In a preferred form, the inner component is formed from an element including a side wall connected on one edge to a top wall and connected on an opposing edge to a bottom wall. The respective edges of the side wall are preferably parallel. It is preferred that the side wall will form the side wall at either the anterior, or more preferably, posterior side. Preferably the side wall is connected on one side edge to one or more other side walls, ideally one. Preferably the side wall is connected on the other side edge to one or more other walls, ideally 4 in the case of a hexagonal core and 6 in the case of an octagonal core. The top and bottom edges of the side walls may be parallel or non-parallel depending upon the locations relative to the top and bottom walls they are to occupy. Preferably all the boundaries between side walls in the strip are parallel to one another.

Preferably the side wall(s), top wall and bottom wall are joined together by stitching and/or other attachment techniques.

One or more of the side walls of the inner component may be reinforced and/or of multiple thickness.

On one or more, preferably all, sides, the inner component may be formed of a plurality of inner components. Such a plurality of inner components may be provided in a spiral form or concentric form. Such a plurality of inner components may be

dimensioned to contact the core.

The outer component may be an outer jacket. The outer component may be of fabric.

The fabric may be formed by flat or circular weaving, knitting, braiding, embroidery or combinations thereof.

The fabric may be formed using one or more of polyester, polypropylene, polyethylene, carbon fibre, glass fibre, glass, polyaramide, metal, copolymers, polylactic acid, polyglycolic acid, biodegradable materials, silk, cellulose, silk worm silk, spider silk or polycaprolactone.

The outer component may entirely surround the inner component and/or encapsulate the inner component. One or more apertures or gaps are preferred in the outer component, ideally to provide fluid communication through the outer component. Preferably a large number of apertures or gaps are provided the material from which the outer component is formed, for instance a woven fabric. The apertures or gaps occurring in the outer component due to the manner of manufacture of the material from which it is formed may be supplemented with further apertures or gaps. The supplementation may be provided by degradation and/or absorption of one or more materials forming the outer component.

The outer component may be configured and/or formed of one or more materials intended to promote tissue growth, particularly tissue ingrowth through the outer component and/or between the inner component and the core and/or through the inner component.

One or more materials used in the outer component may be bio-absorbable and/or soluble and/or degradable, particularly with the spine. The bio-absorbable material may be used to decrease the amount of outer component present and/or positions at which the outer component is present and/or density at which the outer component is present overtime. Areas of bio-absorbable material may be provided. Bio-absorbable fibres may be used to form the outer component. The outer component may be entirely bio-absorbable or only partially. Different materials having different rates of bio-absorption may be used. The may be mixed together in the outer component

other flange on another, preferably opposing, part thereof. Preferably at least one

from which it is formed may be supplemented with further apertures or gaps. The

absorbable material defines the overall shape of the flange(s) and/or maintain the

more in-growth controlling forms. Different in-growth controlling forms may be used

Preferably the kit includes different sized prostheses for different sized patients and/or different sized prostheses sized for different discs of the spine and particularly the lumber region thereof.

The third aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document.

According to a fourth aspect of the invention we provide a surgical technique for providing a disc prosthesis, the technique including, removing at least part of the natural disc in a spine and inserting a disc prosthesis in the spine, the disc prosthesis comprising a core. Preferably the core is provided within an inner component or within an outer component. Preferably the inner component is provided within an outer component.

The technique may be performed anterially or posterially.

The technique may use a pre-assembled prosthesis. Preferably the outer component is inserted into the space and the inner component and core are then inserted. The inner component and core may be provided pre-assembled. A plurality of cores may be inserted into a single outer component.

The method may include forming the core in-situ. For instance, multiple components may be used to form the core. The method may be a minimally invasive surgical technique, particularly where the core is formed in the inner component in-situ. The inner component may be inserted and then filled with the core. The outer component may be inserted then have the inner component provided within it, potentially then being filled with core.

The core material and/or inner component may particularly be formed in-situ according to the technique set out in applicant's UK Patent Application No 0406851.6 filed 26 March 2004 or the additional application filed there on under our reference P208007 on the same day as this application, the contents of which are incorporated herein by reference.

Preferably the level of tension and/or load between the anchor position or positions of the disc prosthesis and the outer component of the disc prosthesis vary between a first time and a second time. The first time may be the time of implantation, for instance 1 hour after implantation, or perhaps 1 day after implantation. The second time may be a time after implantation, for instance at least 30 days, preferably at least 60 days, more preferably at least 100 days and potentially even at least 300 days, after implantation. Preferably the level of tension and/or load is lower at the second time than at the first time. Preferably the level of tension and/or load is lower after biological in-growth has occurred. The ingrowth may be into the outer component and/or inner component and/or flanges. Preferably the range of extension of the spine at the first time is less than the range of extension at the second time. Preferably the transition between the level of load and/or level of tension and/or range of extension at the first time and at the second time is phased or gradual. The transition may occur evenly through out the time between the first time and the second time, but preferably occurs during a time period starting after the first time. The transition may continue after the second time to a still lower level of tension and/or load and/or to a still higher range of extension.

The fourth aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document.

Various embodiments of the invention will now be described, by way of example only, and with reference to the accompanying drawings in which:-

Figure 1 is a plan view of a core suitable for use in the present invention;

Figure 2 is a cross-sectional front view of the core of Figure 1;

Figure 3 is a cross-sectional side view of the core of Figure 1;

Figure 4 is a plan view comparing the profile of a core according to the invention with a natural disc;

Figure 5 illustrates an inner jacket according to the present invention, prior to assembly;

Figure 6 illustrates an outer jacket according to the present invention, prior to assembly;

Figure 7 illustrates an outer jacket according to another embodiment of the present invention, prior to assembly;

50h. These side wall are stitched to the top wall 51 and bottom wall 52 so as to give an octagonal box form to the inner jacket and close completely around the core.

The material used for the inner jacket uses densely packed fibres to define as smooth a surface as possible for the fabric. This is particularly desirable for the inner surfaces which contact the core. This ensures the most uniform contact surface area between the inner jacket and the elastomer core.

Connected to the eighth side wall 50h is the first of a series of additional elements also formed from the same embroidery. These additional elements, in sequence 55b, 55a, 55c, 55d, 55e, 55f, 55g and 55h are wrapped around the side walls 50 of the assembled inner jacket. As a result they form an additional ring of material around the side of the core. In effect this extra band of material strengthens the ability of the inner jacket to act as a natural annulus would and resist expansion sideways by the core when placed under compressive load. The additional elements can be secured with further stitching. The additional elements 55 could of course be provided by a suitably configured, but separate element to the element providing the walls 51, 52, 50.

The side walls 50 and additional elements 55 are provided with a length and height pattern intended to define an inner jacket which matches the length and height variation pattern of the core.

An inner jacket provided in this way offers at least two key benefits.

Firstly it allows the jacket in contact with the core to have relatively low movement levels, whilst still enabling the overall desired level of movement for the artificial disc due to the outer jacket's presence and design. Low movement levels for the inner jacket mean that abrasion of the core is minimised. A single jacket would not achieve this.

Secondly, the inner jacket can be designed with properties ideal for its purpose, whilst allowing the outer jacket to be designed with properties ideal for its purpose. Thus the inner jacket aims to provide as dense and hence smooth a fabric surface as

possible in contact with the core. In this way the risk of individual fibres protruding relative to the others is reduced. Protruding fibres can potentially cause wear due to the micro-motion of the jacket against the core in use. This is a particular potential issue in the context of the high loads encountered in the lumber region. Whilst such properties are desirable here, they are not consistent with those found to be desirable for the outer surface/outer jacket of the artificial disc. Using two separate jackets allows better optimisation in each case.

In a modified embodiment of the inner jacket, its properties may be tailored to facilitate tissue ingrowth into the space between the inner jacket and the core. The formation of a layer of tissue directly between the jacket and the core of the disc should be beneficial in reducing still further wear in the device. Because the dense fibre form used to provide the most smooth surface contacting the core is not the most conducive to tissue ingrowth, the make up of the inner jacket may be carefully controlled to assist.

By forming the inner jacket with a portion of the fibres or material formed of bio-absorbable material, as tissue ingrowth occurs the inner jacket can be partially absorbed to provide further room for the ingrowth. The non-bioabsorbable material of the inner jacket serves to provide the required structure for the inner jacket over its lifetime, supplemented by the assistance provided by the tissue itself. The use of quickly, moderately and slowly absorbed biomaterials in conjunction with non-absorbable materials can provide a gradual transition from the desired function being provided by the inner jacket alone to the point where it is shared between jacket and tissue. In some cases, an entirely bio-absorbable inner jacket may be provided. Various distributions for the non-absorbable and bio-absorbable material are possible in the inner jacket. The non-absorbable material may particularly form the outside of the inner jacket.

In addition to the core and inner jacket, an outer jacket is provided. A suitable outer jacket is illustrated in Figure 6. This is intended to substantially surround the inner jacket. The outer jacket has a bottom wall 60 and top wall 62, which are connected by side wall 64a. Further side walls 64b 64c are provided to one side of side wall 64a. Further side walls 64d, 64e are provided to the other side of side wall 64a. Attached

to the top wall 62 is a sixth side wall 64f. The top, bottom and side walls are connected to one another by stitching. This leaves two sides of the outer jacket open, in effect the openings defined by edges 66 in one case and 68 in the other.

The edge 66 of the bottom wall 60 is provided with a flange 70. This has a hole 72 in it. The edge 66 of the top wall 62 is provided with a flange 74 which is thinner than flange 70, so as to be able to pass through the hole 72 in flange 70. Similarly, the edge 68 of the bottom wall 60 is provided with a flange 76. This has a hole 78 in it. The edge 68 of the top wall 62 is provided with a flange 80 which is thinner than flange 76, so as to be able to pass through the hole 78 in flange 76. To close the remaining two sides, therefore, flanges 70 and 74 and flanges 76 and 80 are interdigitated.

The flanges 70, 74, 76 and 80 are all significantly longer than the height of the disc space the artificial disc is to be used in. As a result the ends 82 of the flanges 70, 74, 76, 80 can be anchored to the vertebra above the disc replacement in the case of flanges 70 and 76 and to the vertebra below the disc replacement in the case of the flanges 74, 80.

A similar outer jacket to that illustrated in Figure 6 is provided in Figure 7. In this case, bottom wall 100 is connected to the top wall 102 by means of side wall 104. Further side walls 106 are provided. Two flanges 108 are provided connected to the top wall 102. These flanges are provided with a hole 110 in each case which is intended to receive the fixing used to collect the device to the spine. These holes are provided towards the ends of the flanges. Close to the top wall 102 two further holes 112 are provided. These have the inner flanges 114 which are connected to the bottom wall 100 passed through them in use, see Figure 8a. These flanges are also provided with holes 110 to receive fixings in use.

In its assembled form, such a disc outer can appear as shown in Figure 8a. Here the flanges 114 are clearly shown as interdigitated with the flanges 110 by virtue of their being passed through the holes 112 therein. The completed structure formed by the bottom wall 100, top wall 102, side wall 104 and further side walls 106, together with the flanges, totally encloses the core. Once again, an octagonal plan view is provided,

Figure 8b, with a similarly shaped octagonal core 116 provided therein, Figure 8c. The core 116 in this case, as with the previous embodiments, is generally centred within the outer jacket.

In the Figure 9a, 9b and 9c embodiment, an additional ring of material is provided around the core, inside the outer jacket 118 by an inner 120. In practice, this provides additional strength to the device when resisting lateral expansion when the core is compressed, i.e. into or out of the paper in the plan view shown in Figure 9c.

The Figure 9a embodiment shows in perspective view the overall assembly consisting of the outer jacket, inner reinforcement and core. In this case an additional annular reinforcement 122 is provided.

The Figure 11a embodiment of the invention provides for a similar outer jacket to that described in Figure 7 above. However, in this case, the side walls 106 are extended by a very substantial amount via a series of additional elements 200a, 200b, 200c etc. A large number of repeats of these additional elements are provided, a number too great to be shown on the Figure 11a drawing sheet. This device is assembled by folding the additional elements, starting at one end, so as to form a spiral of generally octagonal outline. The result is shown in Figure 11b where a spiral 202 is formed extending from the very centre of the device 204, out to its outer wall 206. Such a spiral can provide the core itself, or additional core material can be provided between the turns of the spiral, for instance hydrogel or other material which can be caused to flow into the device and then allowed to set. In Figure 11c, an interdigitated, assembled form of the device of Figure 11a and Figure 11b is shown. The spiral core forms the core function for this device, as well as providing substantial reinforcement against expansion when the device is placed under compression. In effect the spiral provides the core, inner component and outer component in this embodiment.

In Figure 12a, an unassembled form for the inner component is provided, including top wall 220, bottom wall 222, side walls 224 and a large number of additional elements 226a, 226b etc. Once again, these additional elements can be folded so as to provide an octagonal spiral core with the walls 224, 220 and 222 completing the exterior 228 of this inner component. This in turn is received within an outer

component 230, the assembled form for which is shown in Figure 12c. Again, the folded additional elements may form the core on their own or together with other core material, such as hydrogels. Again, a core structure of this type provides substantial resistance to sideways expansion when the device is placed under compression. In the Figure 13 and Figure 14a to 14d illustrations, a form of device is provided in which the centre of the core is correctly located in the centre of the disc space it is to be provided in. This is achieved by the use of a buttress zone formed in the device. This structure for the device allows the fixation flanges, with their interdigitation, to be flush with the anterior surface of the vertebral bodies, but still allow the disc itself to sit recessed by at least 4mm within the disc space. Correct centring of the core, acting as the replacement, is thus provided. Additionally, such replacement reduces the risk of the main body of the device being pinched by the anterior lip of the vertebrae as the spine is flexed.

Whilst it is possible to form the buttress from an entirely separate component, such as a folded fabric, in the preferred format, it is formed from a series of further elements 300 through to 309. In effect, side walls are provided on the left hand side of the device, as seen in the simple plan view in Figure 14a by means of the panel L8, L7, L6 and L4. The right hand side is provided by panels R2, R3. The further elements 300 through to 309 are folded to form the buttress structure. A variety of configurations are possible, but in the illustrated form of Figure 14b, the first part of the buttress is formed by panel 300 which extends inside the outer profile of outer jacket from the edge formed by the contact of panel R3 and L4. Further element 302 extends across the end of panel L5, further element 303 across the inside of panel L6. The further element 304 is then folded back across the inside of further element 303, with further element 305 being across the inside of further element 302. Similarly, further element 306 is provided across the inside of further element 300, before there is a further fold so as to provide further element 307 across the inside of further element 306. Further element 308 is provided across the inside of further element 305 with further element 309 being provided across the inside of the further element 304. Further folds of material can be provided if needed.

An alternative format for the buttress structure, formed in a similar way, is shown in Figure 14c. Here, further elements provided at one end of the outer jacket form the

established as beneficial in the cervical disc.

In designing the artificial lumbar disc the aim has been to provide a disc having appropriate compressive stiffness. The decompression of the spinal cord through the opening of the disc space is one of the key principles in the relief of pain through disc replacement or fusion. To achieve this the artificial disc is provided with a compressive stiffness curve (force against displacement) similar or higher to the natural disc it is intended to replace. The properties of the core can be modified by doping or the like. For instance, the core may be provided with 13% barium sulphate.

Ideally, the artificial disc mimics as many of the motion stiffnesses as possible of a natural disc. Flexion/extension motions are both the most common and the largest (in terms of angle) motions that occur in the lumbar spine. This is the key stiffness which the above artificial disc seeks to match. The ability to carry shear and torsional loads on the disc itself should help protect the facet joints and is therefore also mimicked as far as possible.

One of the intentions with disc prostheses of the above mentioned type and type described in US6093205 is to encourage tissue ingrowth into the disc prosthesis. The ingrowth of such soft tissue into the outer jacket and/or inner jacket and/or flanges may occur. The benefit of this is that biological fixation of the prosthesis in the disc space occurs in the long term and this in turn resists undesirable migration of the prosthesis out of the correct position within the disc space. The flanges and the anchoring they provide are particularly useful in this context as they provide secure fixation of the prosthesis whilst this biological fixation develops over the first few months after implantation. The flanges may also provide a useful scaffold for the development of a biological anterior longitudinal ligament.

Whilst the flanges need to provide a high level of fixation during the first few months after implantation, once ingrowth has occurred this level of fixation is not needed. As a result, the level of tension in the flanges needed to give fixation may be undesirably high in the long term as it resists the full extension range of the spine. This is particularly a potential issue for optimum performance in the case of neck disc prostheses , where the extension range is greater.

To address this issue and provide still further improved disc prostheses, designs have been developed which reduce the tension in the flanges a few months after implantation. This may be through a reduction in the tension or its removal through the detachment of the flanges. As a result, once the biological fixation has had time to develop under preferred conditions and with mechanical restraint of the prosthesis, the prosthesis allows the full range of movement and does not compromise the spines operation long term.

A number of designs suitable for general use in the spine, including lumbar and cervical disc spaces have been developed.

Referring to Figure 15a, an outer jacket in its flat form, before assembly to surround the core, is shown. The core would be surrounded by bottom wall 1100, by the two side walls 1104 and 1106 attached to the bottom wall 1100 and by the top wall 1102. A first pair of flanges 1108a, 1108b extend from the top wall 1102 and are joined together by a web 1110. The web 1110 and flanges 1108a, 1108b define the bounds of a hole 1112. The second pair of flanges 1114a, 1114b are attached to the bottom wall 1100 and in use are passed through the hole 1112 to provide the above mentioned interdigitation. The ends of the flanges 1108a and 1108b both have apertures 1116 which accommodate fixing screws inserted into the spine in use. The ends of the flanges 1114a, 1114b, could be provided with such apertures for fixing screws, but in this case are provided with sections 1118 for receiving sutures, not shown. The operation of this feature is described in more detail below, and of course such a structure could be used in the case of both flange pairs as the fixing.

In a first design approach, the flanges are joined to the rest of the outer jacket which encloses the core by a zone of different material. This different material is made of an absorbable fibre and as a consequence, after the desired controlled period, the zone disappears and so ceases to join the flanges to the outer jacket for the core anymore. As a result, the tension in provided by the flanges is released and the full range of extension is provided. The absorption process would preferably be gradual so as to provide a phase reduction in the tension and hence phased increase in the range of movement.

In a second design approach, the flanges are formed from at least two different material. The flanges include load bearing fibres, which are placed under and maintain the desired tension, and other fibres. The load bearing fibres are made of an absorbable fibre and as a consequence, after the desired controlled period, they are absorbed and so are no longer available to bear the load and the tension is released. The other fibres are intended to be permanent and so are then all that remains of the flanges. These other fibres may serve still to define the overall shape of the flanges, maintain the interdigitation and potentially maintain a reduced level of tension. At least a slackening of the tension results and an increased or even full range of extension is provided. The absorption process would again preferably be gradual so as to provide a phase reduction in the tension and hence phased increase in the range of movement.

In a third design, the flanges include fibres which assume a zigzag path away from the rest of the outer jacket which holds the core and towards the ends of the flanges. When implanted, the zigzag path these fibres take is maintained because these fibres are not subjected to the load applied to the flanges. Instead, that load is borne by other fibres which are attached to the outer jacket and fixation locations. These other fibres are bio-absorbable and so with time disappear. The result is that the load transfers from the other fibres to the zigzag fibres and the zigzag fibres straighten. The result is a slackening of the tension in the flanges and an increase in the range of extension possible.

In a fourth design, the zigzag fibres are again used, but this time together with a series of fibres which bridge the zigzags. The bridging fibres may be stuck to the zigzag fibres and/or wound round them and/or connected to the zigzag fibres in a fixed manner. The overall result is that these bridging fibres prevent the zigzags opening up to a linear form, at the time of implantation, and so prevent the flanges extending, when the desired tension is applied. As the bridging fibres disappear, the load transfers to the zigzag fibres, they straighten, the tension slackens and the extension range for the spine is increased.

In each of these designs, the use of sets of materials in the prostheses means that the transition is made gradual. For instance, slightly different materials and/or different